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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/600,881 | 06/20/2003 | John S. Brandstetter | P-10169.00 | 6677 |
| 27581 | 7590 | 02/15/2006 | EXAMINER | |
| MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924 | | | ALEXANDER, JOHN D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |
| DATE MAILED: 02/15/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/600,881 | Applicant(s) BRANDSTETTER ET AL. | |
| | Examiner John D. Alexander | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/13/04, 2/14/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14, 15, 17, 18, 20, 21, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 are unclear because no step is disclosed for measuring more than one peak amplitude to permit storage of more than one.

Claims 2, 6, 8, 12, 14, 18, 20, and 24 recite the limitation “the measured peak amplitudes” in lines 2 and 3 of each claim. There is insufficient antecedent basis for this limitation in the claims. The limitation should be changed to --the one or more measured peak amplitude--.

Claims 5, 11, 17, and 23 recite the limitations “the amplitude” and “the cardiac signal amplitude” in lines 2 and 3 of each claim. There is insufficient antecedent basis for these limitations in the claims. It is unclear whether Applicant is referring to the measured peak amplitude from Claims 1, 7, 13, and 19 respectively or to a different amplitude.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Henry et al. (Patent No. 5339820). Henry et al. disclose a system and method for adjusting the sensing thresholds of an implantable medical device based on the measured peak amplitudes of the heart's electrical activity and which aim to ensure sensing of diminished amplitudes during tachyarrhythmia episodes (Col. 3, lines 26-61; Col. 6, lines 38-43).

- Regarding “pre-detection criteria”, Henry et al. disclose a maximum period of time during which there is an absence of detected activity (Col. 2, lines 33-35) as well as the detection of low amplitude activity (Col. 4, lines 30-34 & 56-60; Col. 6, lines 40-43), each of which are associated with the potential detection of a tachyarrhythmia episode. Although Henry et al. seem to include Applicant's recitation, examiner notes that the claims as written do not require an active step of detecting particular criteria.
- Regarding the storage of the measured peak amplitudes, examiner considers that Henry et al.'s measurements of peak amplitude are necessarily stored for use in the disclosed computation of sensitivity threshold (Col. 3, lines 53-61).
- Regarding Claims 5 and 17, see Col. 3, lines 46-48 and Col. 6, lines 42-43.

Claims 7-12 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Haefner et al. (Patent No. 5658317). Haefner et al. disclose a system and method for adjusting the sensing thresholds of an implantable medical device based on the measured peak amplitudes of the heart's electrical activity and which aim to ensure sensing of diminished amplitudes during tachyarrhythmia episodes (Col. 1, lines 43-46; Col. 3, lines 47-50).

- Regarding "detection criteria", Haefner et al. disclose that the sensitivity adjustment method is configured to switch to a tailored method upon detection of tachyarrhythmia conditions (Col. 4, lines 25-28; Col. 18, lines 8-19). Although Haefner et al. seem to include Applicant's recitation, examiner notes that the claims as written do not require an active step of detecting particular criteria.
- Regarding the storage of the measured peak amplitudes, Haefner et al. disclose storage registers for peak history information (Fig. 5, elements 82 & 86; Col. 11, lines 1-17).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grevis et al. (Patent No. 4940054) disclose a sensitivity control system and method and teach the use of decreased sensitivity thresholds during periods of suspected and confirmed tachyarrhythmia.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA



JEFFREY R. JASTRZAB
PRIMARY EXAMINER
2/13/06